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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/839,632

04/20/2001

David H. Lynch

3124

2458

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IMMUNEX CORPORATION  
LAW DEPARTMENT  
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SEATTLE, WA 98119

EXAMINER

SCHEINER, LAURIE A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/839,632

Applicant(s)

LYNCH, DAVID H.

Examiner

Laurie A. Scheiner

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/26/01 &amp; 10/21/02</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statements filed 7/26/01 and 10/21/02 have been considered. An initialed copy is enclosed.

### ***Election/Restrictions***

Applicant's election with traverse of \*\*\* in Paper No. \*\*\* is acknowledged. The traversal is on the ground(s) that\*\*\*. This is not found persuasive because\*\*\*.

The requirement is still deemed proper and is therefore made FINAL.

Claim \*\*\* withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected\*\*\*, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No.\*\*\*.

Applicant's election without traverse of \*\*\* in Paper No. \*\*\* is acknowledged.

Applicant's election of Group I (claims 1-10) on August 4, 2004 is acknowledged. Because applicant has canceled all non-elected claims in response to the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-10 should recite --The-- "bispecific antibody" for proper reference to the previously recited claim components.

***Claim Rejections - 35 USC § 102 and 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ashkenazi et al. (WO 00/73349) in view of Ni et al. (US 6,743,625).

Ashkenazi et al. teach antibodies specific for death receptor 4 (DR4; also known as TNF-related apoptosis-inducing ligand (TRAIL) receptor 1) for treatment of various diseases, including cancer (see e.g. pages 7, 41) or infectious diseases (pages 55-56). Specific monoclonal antibodies that bind to the receptor and trigger apoptosis are taught (see e.g. pages 29-30). The antibodies can be monoclonal and/or multispecific, particularly bispecific with the other antibody specificity directed against another cell surface protein or receptor (pages 15, 41-42). The antibodies can be used in combination with other therapeutic agents such as anti-DR5 antibodies (pages 56-57).

Ni et al. teach death receptor 5 (DR5; also known as TNF-related apoptosis-inducing ligand (TRAIL) receptor 2) and antibodies specific therefor. The antibodies may be bispecific,

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specific for both the DR5 polypeptide and a heterologous polypeptide (col. 62, lines 59-65). Anti-DR5 antibodies which activate the receptor are part of the invention for therapeutic methods (cols. 64, 78, 79), including stimulating apoptotic death of cancer cells (cols. 79-81, 84) or cells with infectious agents (col. 87). The antibody can be co-administered with another agent that induces apoptosis (col. 80).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have constructed and used bispecific antibodies with binding sites specific for DR4 and DR5 (TRAIL receptors 1 and 2) in the methods of Ashkenazi et al. and Ni et al. because both Ashkenazi et al. and Ni et al. teach that their respective anti-receptor antibodies can be used as bispecific antibodies in combination with antibodies specific for a heterologous polypeptide, in particular another receptor as taught in Ashkenazi et al., and that their antibodies can be used in combination therapies with other apoptotic-inducing agents, Ashkenazi et al. specifically teaching combinations of anti-DR4 and anti-DR5 antibodies. One of ordinary skill in the would have been motivated to have provided the agents as a bispecific antibody in view of the direct suggestions in both Ashkenazi et al. and Ni et al. to do so.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Salcedo et al. (US 2003/0228309) teach structural aspects of bispecific antibodies but appear to teach away from their production for use (see e.g. page 8 ¶ [0064]).

#### ***Status of the Claims***

No claim is allowed.

#### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (571) 272-0910. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571) 272-1600.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Laurie Scheiner/LAS  
March 18, 2005



Laurie Scheiner  
Primary Examiner  
Art Unit 1648